

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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LISA KURTZ and NORMAN KURTZ,

Plaintiffs,

**07 CIV 6505  
(UA) (NRB)**

- against -

C.B. FLEET HOLDING COMPANY, INCORPORATED,  
C.B. FLEET COMPANY, INC., GENOVESE DRUG  
STORES, INC., ECKERD CORPORATION, and  
ECKERD STORE #5605,

**ANSWER**

**TRIAL BY JURY  
DEMANDED**

Defendants.

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Defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B.  
FLEET COMPANY, INC., by their attorneys, HEIDELL, PITTONI, MURPHY & BACH, LLP,  
upon information and belief, answer the complaint herein as follows:

**AS AND TO THE SECTION OF THE COMPLAINT  
DESIGNATED "PARTIES"**

1. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated "1."
2. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated "2."
3. Admit the allegations contained in the paragraph of the complaint designated "3."
4. Admit the allegations contained in the paragraph of the complaint designated "4."
5. Deny the allegations contained in the paragraph of the complaint designated "5" except admit that at certain times not specifically set forth in the complaint C.B.

FLEET COMPANY, INC. manufactured, distributed and sold a pharmaceutical product known as Fleet® Phospho-soda®, a sodium phosphates oral solution made from monobasic sodium phosphate and dibasic sodium phosphate, in accordance with all applicable laws and regulations; Phospho-soda was sold as an over-the-counter product for use as a laxative for relief of occasional constipation; Phospho-soda was sold for the separate and independent use as a bowel cleanser in preparation for certain medical procedures only upon the prescription or direction of a duly licensed physician pursuant to instruction provided by the physician in accordance with the warnings and other information contained in the professional use labeling available to physicians. Any characterization of the product warning that is inconsistent with the product labeling or professional use labeling is denied.

6. Deny the allegations contained in the paragraph of the complaint designated “6” except admit that at certain times not specifically set forth in the complaint C.B. FLEET COMPANY, INC. manufactured, distributed or sold Phospho-soda through interstate commerce including New York State.

7. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated “7.”

8. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated “8.”

9. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated “9.”

10. Deny the allegations contained in the paragraph of the complaint designated “10” insofar as they pertain to answering defendants, except admit that C.B. FLEET

COMPANY, INC. distributes and sells products in the State of New York and otherwise deny knowledge or information sufficient to form a belief as to the remaining allegations of this paragraph and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

**AS AND TO THE SECTION OF THE COMPLAINT  
DESIGNATED "FACTS"**

11. Admit the allegations contained in the paragraph of the complaint designated "11" and by way of further answer, incorporate their response to paragraph "5."
12. Deny the allegations contained in the paragraph of the complaint designated "12" in the manner alleged and by way of further answer, incorporate their response to paragraph "5."
13. Deny the allegations contained in the paragraph of the complaint designated "13" in the manner alleged except admit that 45mL of Fleet Phospho-soda contains 8.1 grams of dibasic sodium phosphate heptahydrate and 21.6 grams of monobasic sodium phosphate monohydrate.
14. Deny the allegations contained in the paragraph of the complaint designated "14" in the manner alleged except admit that at certain times not specifically set forth in the complaint, that the Tentative Final Monograph for laxative drug products provided that the "oral dosage" for adults and children over 12 years of age is sodium phosphate 3.42 to 7.56 grams, and sodium biphosphate 9.1 to 20.2 grams in a single daily dose, which was modified by final rule dated May 21, 1998 to include the following language: "Do not take more unless directed by a doctor. See warnings."
15. Deny the allegations contained in the paragraph of the complaint designated "15" in the manner alleged except admit that at certain times not specifically set forth

in the complaint, Phospho-soda was sold for the separate and independent use as a bowel cleanser in preparation for certain medical procedures including a colonoscopy, only upon the prescription or direction of a duly licensed physician and dosing and timing instructions were prescribed and/or directed by a duly licensed physician in accordance his or her medical judgment and with warnings and other information contained in the professional use labeling available to physicians. By way of further answer, answering defendants incorporate their response to paragraph "5."

16. Deny the allegations contained in the paragraph of the complaint designated "16" in the manner alleged except admit only that 90 mL of Fleet Phospho-soda contains 16.2 grams of dibasic sodium phosphate heptahydrate and 43.2 grams of monobasic sodium phosphate monohydrate. By way of further answer, the TFM does not specifically limit the professional use of sodium phosphates as part of a bowel cleansing regimen. By way of further answer, answering defendants incorporate their response to paragraph "5."

17. Deny the allegations contained in the paragraph of the complaint designated "17" in the manner alleged except admit that at certain times not specifically set forth in the complaint, the Food and Drug Administration ("FDA") issued a Tentative Final Monograph ("TFM") for oral saline laxatives that Fleet has sought to amend to include a professional dosing regimen as Generally Recognized as Safe. By way of further answer, FDA has yet to issue a response to Fleet's petition.

18. Deny the allegations contained in the paragraph of the complaint designated "18" in the manner alleged except admit that at certain times not specifically set forth

in the complaint, the Food and Drug Administration ("FDA") issued a Tentative Final Monograph ("TFM") for oral saline laxatives. By way of further answer, answering defendants incorporate their response to paragraph "17."

19. The allegations contained in the paragraph of the complaint designated "19" are admitted. By way of further answer, answering defendants incorporate their response to paragraph "16."

20. As to the allegations contained in the paragraph of the complaint designated "20", answering defendants admit only that as of February 4, 2003, C.B. FLEET COMPANY, INC. had received rare reports of renal injury following use of Phospho-soda mainly in contraindicated or overdosed patients. The remaining allegations contained in the paragraph of the complaint designated "20" are denied. By way of further answer, answering defendants incorporate their responses to paragraphs "5" and "15."

21. As to the allegations contained in the paragraph of the complaint designated "21", answering defendants admit only that Phospho-soda may be associated with certain conditions and/or risks as set forth in the professional use labeling. By way of further answer, answering defendants incorporate their responses to paragraphs "5" and "15."

22. Deny the allegations contained in the paragraph of the complaint designated "22". By way of further answer, answering defendants incorporate their responses to paragraphs "5" and "15."

23. Deny the allegations contained in the paragraph of the complaint designated "23". By way of further answer, answering defendants incorporate their responses to paragraphs "5" and "15."

24. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraphs of the complaint designated "24" regarding plaintiff's purchase of the product. Otherwise the allegations of the paragraph designated "24" constitute conclusions of law to which no response is required and answering defendants beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

25. Deny the allegations contained in the paragraph of the complaint designated "25" in the manner alleged and by way of further answer, incorporate their responses to paragraph "5" and "15."

26. The allegations contained in the paragraph of the complaint designated "26" are denied. By way of further answer, Phospho-soda was sold for use as a laxative with directions, warnings and safety information contained in the product labeling. Phospho-soda was sold for the separate and independent use as a bowel cleanser in preparation for certain medical procedures including a colonoscopy, only upon the prescription or direction of a duly-licensed physician pursuant to instruction provided by the physician in accordance with warnings and other information contained in the professional use labeling available to physicians. Any characterization of the product warning that is inconsistent with the product labeling or professional labeling is denied. Answering defendants further incorporate their responses to paragraphs "5" and "15."

27. Deny the allegations contained in the paragraph of the complaint designated "27" in the manner alleged except admit that at certain times not specifically set forth in the complaint that the professional use labeling for Phospho-soda published in the Physicians

Desk Reference contained references to independent published medical literature relating to the professional use of Phospho-soda as a bowel cleanser. By way of further answer, answering defendants incorporate their responses to paragraph "5," "15" and "26."

28. Deny the allegations in the paragraph of the complaint designated "28" in the manner alleged. By way of further answer, the active ingredients and excipients of Phospho-soda are each characterized by slow and incomplete absorption into the blood stream from the gastrointestinal tract.

29. As to the allegations contained in the paragraph of the complaint designated "29," answering defendants admit only that Phospho-soda may be associated with certain conditions and/or risks as set forth in the professional use labeling. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

30. In response to the paragraph of the complaint designated "30," answering defendants admit only that alternative bowel cleansers and purgatives are available each with attendant risks. The remaining allegations contained in the paragraph of the complaint designated "30" are denied. By way of further answer, the appropriate bowel cleansing regimen for a given patient should be determined by his or her physician and answering defendants incorporate their responses to paragraphs "5," "15" and "26."

31. In response to the paragraph of the complaint designated "31," answering defendants admit only that alternative bowel cleansers and purgatives are available each with attendant risks. The remaining allegations contained in the paragraph of the complaint designated "31" are denied. By way of further answer, the appropriate bowel cleansing regimen for a given patient should be determined by his or her physician and answering defendants incorporate their responses to paragraphs "5," "15" and "26."

32. In response to the paragraph of the complaint designated "32," answering defendants admit only that alternative bowel cleansers and purgatives are available each with attendant risks. The remaining allegations contained in the paragraph of the complaint designated "32" are denied. By way of further answer, the appropriate bowel cleansing regimen for a given patient should be determined by his or her physician and answering defendants incorporate their responses to paragraphs "5," "15" and "26."

33. Deny the allegations contained in the paragraph of the complaint designated "33" in the manner alleged.

34. Deny the allegations contained in the paragraph of the complaint designated "34" in the manner alleged, except admit that at certain times not specifically set forth in the complaint the 3.0 ounce package of Phospho-soda® stated "[w]hen taken as directed, laxative action is gentle, virtually free from the likelihood of gastrointestinal discomfort or irritation, and is safe for the age groups indicated." It is further denied that answering defendants made any express representations to plaintiff in connection with the use of the product as a bowel cleanser. Answering defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the paragraph of the complaint designated "34" with regard to the allegation that plaintiff was in any particular age group at the time she allegedly used the product and beg leave to refer all questions of law to the court and all question of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

35. Deny the allegations contained in the paragraph of the complaint designated "35" and beg leave to refer all questions of law to the court and all questions of fact

to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

36. Deny the allegations contained in the paragraph of the complaint designated "36" concerning any "misrepresentations regarding Fleet Phospho-soda and the dangers and health risks associated with the product" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

37. Deny the allegations contained in the paragraph of the complaint designated "37" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

38. Deny the allegations contained in the paragraph of the complaint designated "38" that answering defendants made misrepresentations concerning Phospho-soda. Answering defendants are without knowledge or information sufficient to form a belief as to the remaining allegations set forth in the paragraph of the complaint designated "38" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

39. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated "39."

40. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated "40" regarding plaintiff's

actual purchase and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. The remaining factual allegations of the paragraph are denied. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

41. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated as "41" regarding plaintiff's actual purchase and doctor's recommendation, and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. The remaining factual allegations of the paragraph are denied. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

42. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the amended complaint designated "42" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

43. Deny the allegations contained in the paragraph of the complaint designated "43" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

44. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated "44."

45. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated "45."

46. Deny knowledge or information sufficient to form a belief as to the allegations contained in the paragraph of the complaint designated "46."

47. Deny the allegations contained in the paragraph of the complaint designated "47" as they pertain to Phospho-soda® and otherwise deny knowledge or information sufficient to form a belief as to the remaining allegations and beg leave to refer all questions of law to the court and all question of fact to the trier thereof.

48. The allegations of the paragraph designated "48" constitute conclusions of law to which no response is required and answering defendants beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

49. Deny the allegations contained in the paragraph of the complaint designated "49" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

50. The allegations of the paragraph designated "50" constitute conclusions of law to which no response is required and answering defendants otherwise beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

#### **AS AND TO THE FIRST CAUSE OF ACTION**

51. Answering the paragraph of the complaint designated "51," answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "50" with the same force and effect as if herein set forth at length.

52. Deny the allegations contained in the paragraph of the complaint designated "52" and beg leave to refer all questions of law to the court and all questions of fact

to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

53. Deny the allegation that Fleet® Phospho-soda® increased the "risk of kidney disease and other dangers and health risks" and therefore deny the allegations contained in the paragraph of the complaint designated "53" in their entirety.

54. As to the allegations contained in the paragraph of the complaint designated "54," answering defendants admit that they expected that Phospho-soda would reach certain users without substantial change from, or alteration of, the condition in which it was originally manufactured and sold. By way of further answer, when used as a bowel cleanser, answering defendants expected that the product would be prescribed or directed for use by a duly licensed physician with instructions for use provided by the physician in accordance with the warnings and other information contained in the professional use labeling available to physicians.

55. Deny the allegations contained in the paragraph of the complaint designated "55" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

56. Deny the allegations contained in the paragraph of the complaint designated "56" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

57. Deny the allegations contained in the paragraph of the complaint designated "57" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**AS AND TO THE SECOND CAUSE OF ACTION**

58. Answering the paragraph of the complaint designated "58," answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "57" with the same force and effect as if herein set forth at length.

59. Deny the allegations contained in the paragraph of the complaint designated "59" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

60. Deny the allegations contained in the paragraph of the complaint designated "60" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

61. Deny the allegations contained in the paragraph of the complaint designated "61" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

62. Deny the allegations contained in the paragraph of the complaint designated "62" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

63. Deny the allegations contained in the paragraph of the complaint designated "63" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**AS AND TO THE THIRD CAUSE OF ACTION**

64. Answering the paragraph of the complaint designated "64" answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "63" with the same force and effect as if herein set forth at length.

65. Deny the allegations contained in the paragraph of the complaint designated "65" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

66. Deny the allegations contained in the paragraph of the complaint designated "66" and beg leave to refer all questions of law to the court and questions of fact to the trier thereof.

67. Deny the allegations contained in the paragraph of the complaint designated "67" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**AS AND TO THE FOURTH CAUSE OF ACTION**

68. Answering the paragraph of the complaint designated "68," answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "67" with the same force and effect as if herein set forth at length.

69. Deny the allegations of the paragraph of the complaint designated "69" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

70. Deny the allegations of the paragraph of the complaint designated "70" in the manner alleged and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

71. Deny the allegations of the paragraph of the complaint designated "71" in the manner alleged and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

72. Deny the allegations contained in the paragraph of the complaint designated "72" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

73. Deny the allegations contained in the paragraph of the complaint designated "73" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**AS AND TO THE FIFTH CAUSE OF ACTION**

74. Answering the paragraph of the complaint designated "74," answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "73" with the same force and effect as if herein set forth at length.

75. Deny the allegations contained in the paragraph of the complaint designated "75" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

76. Deny the allegations contained in the paragraph of the complaint designated "76" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

77. Deny the allegations contained in the paragraph of the complaint designated "77" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**AS AND TO THE SIXTH CAUSE OF ACTION**

78. Answering the paragraph of the complaint designated "78" answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "77" with the same force and effect as if herein set forth at length.

79. Deny the allegations contained in the paragraph of the complaint designated "79." It is further denied that answering defendants made any express representations to plaintiff in connection with the use of the product as a bowel cleanser.

80. Deny the allegations contained in the paragraph of the complaint designated "80" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

81. Deny the allegations contained in the paragraph of the complaint designated "81" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

82. Deny the allegations contained in the paragraph of the complaint designated "82" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**AS AND TO THE SEVENTH CAUSE OF ACTION**

83. Answering the paragraph of the complaint designated "83" answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "82" with the same force and effect as if herein set forth at length.

84. Deny the factual allegations contained in the paragraph of the complaint designated "84" beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15," "26" and "34."

85. Deny the factual allegations contained in the paragraph of the complaint designated "85" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15," "26" and "84."

86. Deny the allegations contained in the paragraph of the complaint designated "86" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15," "26" and "84."

87. Deny the factual allegations contained in the paragraph of the complaint designated "87" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**AS AND TO THE EIGHTH CAUSE OF ACTION**

88. Answering the paragraph of the complaint designated "88," answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "87" with the same force and effect as if herein set forth at length.

89. The allegations of the paragraph of the complaint designated "89" constitute conclusions of law to which no response is required and answering defendants otherwise beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

90. Deny the allegations contained in the paragraph designated "90" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

91. Deny the allegations contained in the paragraph of the complaint designated "91" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**AS AND TO THE NINTH CAUSE OF ACTION**

92. Answering the paragraph of the complaint designated "92," answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "91" with the same force and effect as if herein set forth at length.

93. Deny the allegations contained in the paragraph of the complaint designated "93." It is further denied that answering defendants made any express representations to plaintiff in connection with the use of the product as a bowel cleanser.

94. Deny the allegations contained in the paragraph of the complaint designated "94." By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

95. Deny the allegations contained in the paragraph of the complaint designated "95" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

96. Deny the allegations contained in the paragraph of the complaint designated "96" regarding any "misrepresentations" as well as plaintiff's reliance and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

97. Deny the allegations contained in the paragraph of the complaint designated "97" and beg leave to refer all questions of law to the court and all questions of fact

to the trier thereof. By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

98. Deny the allegations contained in the paragraph of the complaint designated "98." By way of further answer, answering defendants incorporate their responses to paragraphs "5," "15" and "26."

99. Deny the allegations contained in the paragraph of the complaint designated "99" and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**AS AND TO THE TENTH CAUSE OF ACTION**

100. Answering the paragraph of the complaint designated "100," answering defendants repeat and reallege each and every denial and admission in answer to the paragraphs of the complaint designated "1" through "99" with the same force and effect as if herein set forth at length.

101. Deny the allegations contained in the paragraph of the complaint designated "101" insofar as the allegations pertain to the answering defendants and otherwise deny knowledge or information sufficient to form a belief as to the allegations of this paragraph and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

102. Deny the allegations contained in the paragraph of the complaint designated "102" insofar as the allegations pertain to the answering defendants and otherwise

deny knowledge or information sufficient to form a belief as to the allegations of this paragraph and beg leave to refer all questions of law to the court and all questions of fact to the trier thereof.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

**FOR A FIRST DEFENSE**

103. This action was not commenced against the answering defendants until after the expiration of the time period specified in the applicable statute(s) of limitations for each cause of action and any recovery based on the alleged causes of action herein is barred.

**FOR A SECOND DEFENSE**

104. That the equitable share of liability, if any, of answering defendants shall be determined pursuant to the provisions of Article 16 of the CPLR.

**FOR A THIRD DEFENSE**

105. Plaintiffs' claims are barred under the learned intermediary or sophisticated user doctrine.

**FOR A FOURTH DEFENSE**

106. That whatever damages may have been sustained at the time and place alleged in the complaint by plaintiffs were caused, in whole or in part, by the culpable conduct of plaintiff and without any negligence on the part of the answering defendants. Damages, if any, are to be diminished proportionally to the culpable conduct of plaintiff.

**FOR A FIFTH DEFENSE**

107. If the plaintiff sustained the injuries and damages as alleged, then said injuries and damages resulted from the plaintiff's knowing and voluntary assumption of the risk of the use of the product.

**FOR A SIXTH DEFENSE**

108. Plaintiffs have failed to mitigate their alleged damages claimed herein.

**FOR A SEVENTH DEFENSE**

109. The amount of alleged damages claimed by plaintiffs should be reduced pursuant to CPLR § 4545 to the extent of any collateral source benefits, remuneration or compensation received.

**FOR AN EIGHTH DEFENSE**

110. That plaintiffs' alleged injuries, if any, were not the result of any act or omission on the part of answering defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., but exist by reason of operation of nature or idiosyncratic or allergic reaction over which the answering defendants had no control.

**FOR A NINTH DEFENSE**

111. If the plaintiffs sustained the injuries and damages alleged, then said injuries and damages resulted from the plaintiff's misuse of the product in such a manner as was not and could not reasonably be anticipated by the answering defendants.

**FOR A TENTH DEFENSE**

112. If the plaintiff sustained the injuries and damages alleged, then said injuries and damages would not have occurred but for the fact that the product was altered or modified by a third party after it left the answering defendants' possession and control. Said

alteration or modification was not made in accordance with the instructions of the answering defendants and was not the result of conduct that reasonably should have been anticipated by the answering defendants.

**FOR AN ELEVENTH DEFENSE**

113. If plaintiffs sustained the injuries and damages alleged, then said injuries and damages were proximally caused by persons and/or entities not connected with the answering defendants and currently unknown to answering defendants and for whom answering defendants bear no responsibility.

**FOR A TWELFTH DEFENSE**

114. That plaintiffs' injuries and damages, if any, were caused exclusively by the intervening, superseding negligence of others.

**FOR A THIRTEENTH DEFENSE**

115. That the product allegedly designed, manufactured, distributed, labeled and sold by defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC. was state of the art at the time of its sale and was manufactured, prepared and labeled according to the generally recognized and prevailing standards in existence at time of its sale, and the state of knowledge or state of the art at time of manufacture and labeling of the product did not reasonably permit defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC. to know about, or to take steps sufficient to alleviate, the alleged risk of which plaintiffs complain, assuming such risk ever existed.

**FOR A FOURTEENTH DEFENSE**

116. That the product is not unreasonably dangerous.

**FOR A FIFTEENTH DEFENSE**

117. That plaintiffs' injuries were not reasonably foreseeable.

**FOR A SIXTEENTH DEFENSE**

118. Plaintiffs' claims are barred, because the benefits of the products at issue outweighed the risks, if any, that might be associated with the products.

**FOR A SEVENTEENTH DEFENSE**

119. That if the plaintiffs were injured as alleged in the complaint, the answering defendants' alleged failure to provide proper or adequate warnings, instructions and labeling assuming answering defendants had such duty, was not the proximate cause of such injuries.

**FOR AN EIGHTEENTH DEFENSE**

120. The answering defendants did not have actual or constructive notice of the defects alleged or dangerous conditions.

**FOR A NINETEENTH DEFENSE**

121. That one or more of the causes of action in the complaint fail to state a cause of action upon which relief may be granted.

**FOR A TWENTIETH DEFENSE**

122. Pursuant to New York law and Restatement (Second) of Torts, section 402A, comment k, and Restatement (Third) of Torts, section 6, the product at issue is not deemed defective or unreasonably dangerous given that such product was accompanied by proper directions and adequate warnings.

**FOR A TWENTY-FIRST DEFENSE**

123. The complaint fails to plead the necessary elements of fraud/deceit.

**FOR A TWENTY-SECOND DEFENSE**

124. The complaint fails to state a cause of action pursuant to General Business Laws §§ 349 and 350.

**FOR A TWENTY-THIRD DEFENSE**

125. The complaint fails to state a cause of action pursuant to General Business Law § 349 and General Business Law § 350. Plaintiffs' claim for statutory fraud based upon answering defendants' alleged violations of General Business Law § 349 and § 350 are barred because answering defendants' advertising complies with the rules and regulations and the statutes administered by the Federal Trade Commission including but not limited to 15 U.S.C. § 45, 15 U.S.C. § 52, 15 U.S.C. § 55, and 16 C.F.R. § 255.1 as well as Food and Drug Administration regulations.

**FOR A TWENTY-FOURTH DEFENSE**

126. Plaintiffs' claims are barred by the doctrine of federal preemption to the extent that FDA directed answering defendants to limit the consumer package labeling to the over-the-counter laxative use of Phospho-soda and to not provide professional use information or professional labeling towards consumers.

**FOR A TWENTY-FIFTH DEFENSE**

127. Plaintiffs' damages are barred or limited by virtue of the fact that the injuries asserted are due to a preexisting condition and are not the result of the use of Fleet® Phospho-soda®.

**FOR A TWENTY-SIXTH DEFENSE**

128. That any cause of action premised on breach of warranty, express or implied, is barred by the applicable provisions of N.Y.U.C.C.

**FOR A TWENTY-SEVENTH DEFENSE**

129. Discovery may show that the plaintiffs' claims are barred or limited by virtue of the fact that plaintiff was not a foreseeable user of Fleet® Phospho-soda®.

**FOR A TWENTY-EIGHTH DEFENSE**

130. That the complaint does not set forth a basis for punitive damages.

**FOR A TWENTY-NINTH DEFENSE**

131. That any claims for punitive damages contained in the complaint fail to state a claim upon which relief may be granted, violate various provisions of the Constitution of the United States and the State of New York, and violate various statutory proscriptions thereof.

**FOR A THIRTIETH DEFENSE**

132. With respect to plaintiffs' demand for punitive damages, answering defendants specifically incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards, including but not limited to, those standards of limitation which arose in *BMW of North America v. Gore*, 116 U.S. 1589 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007).

**FOR A THIRTY-FIRST DEFENSE**

133. The answering defendants allege that they committed no act or omission that was malicious, oppressive, willful, wanton, reckless or grossly negligent and therefore, any award of punitive damages is barred.

**FOR A THIRTY-SECOND DEFENSE**

134. If the plaintiffs sustained the injuries and damages as alleged, then said injuries and damages resulted from the plaintiff's failure to use the product properly, or negligent use of the product.

**FOR A THIRTY-THIRD DEFENSE**

135. The answering defendants incorporate all of the defenses set forth under General Business Law §§ 349 and 350.

**FOR A THIRTY-FOURTH DEFENSE**

136. The plaintiff provided her informed consent.

**FOR A THIRTY-FIFTH DEFENSE**

137. To the extent that plaintiffs request attorneys' fees, such request is improper under applicable law.

**FOR A THIRTY-SIXTH DEFENSE**

138. The answering defendants deny any paragraph or any portions of any paragraph in the complaint not previously referred to herein.

**FOR A THIRTY-SEVENTH DEFENSE**

139. The answering defendants give notice that they intend to rely upon such other defenses as may become available or appear during discovery in this case or otherwise, and hereby reserves the right to amend this Answer to assert any such defenses.

WHEREFORE, defendants C.B. FLEET HOLDING COMPANY, INCORPORATED and C.B. FLEET COMPANY, INC., demand judgment dismissing the complaint herein, together with the costs and disbursements of this action.

Dated: New York, New York  
September 18, 2007

Respectfully submitted,

HEIDELL, PITTONI, MURPHY & BACH, LLP

By:

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